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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,641	11/21/2000	Lisa J. Gerrard	P0645P4D2C3	9837

7590 10/02/2002

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EXAMINER
LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/717,641	Applicant(s) GERRARD ET AL.	
	Examiner David Lambertson	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-100* is/are pending in the application.

4a) Of the above claim(s) *53-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *89-100* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Notice to comply* .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II in Paper No. 8 is acknowledged.

Claims 53-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

Claims 89-100 are considered for examination in the pending application.

Specification

The disclosure is objected to because of the following informalities: on page 20, line 5, applicant misspells "*Escherichia coli*" as "*Escherichia cola*".

Appropriate correction is required.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1,821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 C.F.R. 1.821-1.825) although examination is not precluded by this non-compliance.

Specifically, there are sequences that are not identified with sequence numbers located in TABLES VI-XV, as well as throughout the specification. On page, 36, lines 6 and 52, applicant

lists KSYR, which appears to be an amino aid sequence, but is not identified by a SEQ ID NO, and does not appear in the sequence listing. Additional sequences that are not in compliance are located on page 7 (lines 12, 21, 22 and 33), page 36 (lines 51 and 52), page 37 (lines 3-6) and page 55 (line 30). Also, applicant provides SEQ ID NOS and a sequence listing for nucleotide sequences disclosed in Table B1 and B2, applicant does not provide SEQ ID NOS and a sequence listing for the corresponding amino acid sequences. Applicant is required to return a copy of the attached Notice to Comply with the response.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefore..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 93, and 96 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 12 of prior U.S. Patent No. 6,040,136 (henceforth referred to as the '136 patent). This is a double patenting rejection.

Claims 93 and 96 of the instant application teach a replicable expression vector which can be a replicable phagemid vector comprising a gene fusion of two polypeptides wherein a suppressible termination codon is between the two genes, further limited in that the second polypeptide comprises a filamentous bacteriophage coat protein III or portion thereof.

Claim 12 of the '136 patent also teaches a phagemid expression vector containing a suppressible stop codon between the first and second genes of a gene fusion, where the second gene is encoded by at least a portion of the bacteriophage gene III coat protein. Therefore, claims 93 and 96 of the instant application are anticipated by claim 12 of the '136 patent. Furthermore, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the patent issued from the '136 patent, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 99 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 and 14 of U.S. Patent No. 6,040,136.

Claim 99 of the instant application teaches a phagemid expression vector comprising a gene fusion of an antibody and at least a portion of filamentous bacteriophage coat protein III, where a suppressible stop codon is located between the two genes in the fusion. Claim 14 of the '136 teaches that the first polypeptide of a gene fusion in a phagemid expression vector may be

an antibody (immunoglobulins) or fragments thereof. Claim 12 of the '136 patent teaches a phagemid expression vector containing a suppressible stop codon between the first and second genes of a gene fusion, where the second gene is encoded by at least a portion of the bacteriophage gene III coat protein. Both claims 12 and 14 are dependent on claim 1 of the '136 patent, thus it would have been obvious to apply the limitations of claim 12 to those of claim 14. The ordinary skilled artisan would have been motivated to combine these limitations in order to diversify the number of polypeptides available for expression as gene fusions in the phagemid expression vector, thereby increasing the number of polypeptides that could be examined for binding factors by a method using the expression vector. Given the teachings of the stated prior art and the level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention. Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. Also, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the patent issued from the '136 patent, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

Claims 94, 97 and 100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12 and 14 of U.S. Patent No. 6,040,136. Although the conflicting claims are not identical, they are not patentably distinct from each other

because the instant claims relate to host cells comprising replicable expression vectors that are patented in claims 12 and 14 of the '136 patent. The claims teaching these vectors (93, 96 and 99 of the instant application) are rejected by statutory (93 and 96) and non-statutory (99) double patenting standards. Since the function of the host cells in the instant application is to contain the vectors for purposes of replication, the host cells are representative of the vectors themselves. Thus, the host cells comprising the vectors in the instant application are anticipated by the claims describing the vectors in the '136 patent, although the host cells are not explicitly claimed in the '136 patent. Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. Also, if both patents are issued and the patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the patent issued from the '136 patent, then two different assignees would hold a patent to the same claimed invention and thus improperly there would be possible harassment by multiple assignees.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 89-92, 95 and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by George, et al. (US Patent No. 4,673,641).

George, et al., teaches "a recombinant plasmid which encodes a fusion protein [that] is altered at the junction of the two gene sequences...A chain termination sequence such as amber (TAG), ochre (TAA), or opal (TGA) is located in between the two gene sequences..." (see column 10, lines 17-23). In the absence of disclosure of a specific antibody and because an antibody is a protein, George, et al., also teaches the use of an antibody as the first polypeptide in the gene fusion. Considering the definition of "portion of" as set forth above (see 112 rejections), any amino acid that is present in bacteriophage coat protein III can serve as a portion of bacteriophage coat protein III. Since all proteins contain at least one of the same amino acid, the claim as written reads on a gene fusion between any two polypeptides. Thus George, et al., anticipates the gene fusion as described in claims 89-92, 95 and 98 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 90-92, 95 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over George, et al., in view of Smith (*Science* **228**: 1315-1317 (1985)).

Applicant's invention describes gene fusions between a first polypeptide (which may be an antibody) and a second polypeptide, where the second polypeptide is at least a portion of bacteriophage coat protein III, and the two genes are separated by a suppressible termination codon.

George, et al., teaches "a recombinant plasmid which encodes a fusion protein [that] is altered at the junction of the two gene sequences...A chain termination sequence such as amber (TAG), ochre (TAA), or opal (TGA) is located in between the two gene sequences..." (see column 10, lines 17-23). In the absence of disclosure of a specific antibody and because an antibody is a protein, George, et al., also teaches the use of an antibody as the first polypeptide in the gene fusion. George, et al., does not describe the use of bacteriophage coat protein III as the second polypeptide in the gene fusion.

Smith teaches a gene fusion between a heterologous protein and bacteriophage coat protein III (see page 1315).

George, et al., is modified by Smith to include the use of bacteriophage coat protein III in the gene fusion contained within the phagemid expression vector. The ordinary skilled artisan would have been motivated to combine these teachings in order to provide an efficient means of displaying the polypeptide of the first gene in the fusion at the surface of phagemid particles, as taught by Smith. It would have been obvious to combine these teachings because bacteriophage coat protein III is a protein, any of which can serve as the second polypeptide in a gene fusion.

Given the teachings of the stated prior art and the level of skill of the ordinary skilled artisan at the time of the applicants' invention, it must be considered that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
September 30, 2002

DAVID GUZO
PRIMARY EXAMINER